K121426

Synergetics™

Page 1 of 2

510 (k) Summary of Safety and Effectiveness
Synergetics Disposable Spetzler-Malis Standard Bipolar Forceps
Submitted in accordance with the requirements of 21 CFR 807.92

Applicant's Name and Address:	Synergetics, Inc. 3845 Corporate Centre Drive O'Fallon, MO 63368
Contact Person:	Gary Oliveros Synergetics, Inc. Senior Regulatory Affairs Specialist Telephone Number: (636) 794-5107 Fax Number: (636) 794-5120 Email: goliveros@synergeticsusa.com
Date Prepared:	May 11, 2012
Device Trade Name:	Synergetics™ Disposable Spetzler™ Malis® Standard Bipolar Forceps
Common Name:	Single Use Bipolar Forceps
Device Classification:	21 CFR Part 878.4400, Electrosurgical Cutting and Coagulation Devices and Accessories are Class II devices
Classification Name:	Electrosurgical, Cutting and Coagulation and Accessories
Product Code:	GEI
FDA Panel:	General and Plastic Surgery
Predicate Device:	Synergetics Disposable Spetzler Malis Dual Irrigating Bipolar Forceps, K110924

JUL 10 2012

Device Description:

The Synergetics™ Disposable Spetzler™ Malis® Standard Bipolar Forceps are sterile single use devices for use in electrosurgery. The forceps are a bayonet style and include a cord at the proximal end which allows for connection to a Malis bipolar electrosurgical generator.

Intended Use:

The Synergetics Disposable Spetzler-Malis Standard Bipolar Forceps are single use devices sold sterile and are intended for use in electrosurgery for coagulation of tissue.

Comparison of Technical Characteristics:

Criteria	Predicate Device – Synergetics Single Use Dual Irrigating Bipolar Forceps, K110924	Synergetics Disposable Standard Bipolar Forceps
Intended Use	Sterile single use, for use in electrosurgery for coagulation and irrigation of tissue.	Sterile single use, for use in electrosurgery for coagulation of tissue.
For Use With	Electrosurgical generators, irrigation modules and irrigation tubing	Electrosurgical generators
Forceps Design	Bayonet Style	Bayonet Style
Patient Contact Material	Biocompatible Silver plated Aluminum base with PVDF insulation	Biocompatible Silver plated Aluminum base with PVDF insulation
Electrical Safety Testing	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-2	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-2
Latex Free	Yes	Yes
Single Use	Yes	Yes
Sterilization Method	Ethylene Oxide (EO)	Ethylene Oxide (EO)
Packaging	Rigid PETG Tray, Tyvek lid	Rigid PETG Tray, Tyvek lid
Note 1: Synergetics packaging configuration has been validated in accordance with ISO 11607-1:2006, Packaging for Terminally Sterilized Medical Devices- Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging Systems		

Risk Management:

Risk Management has been implemented and complies with ISO 14971, Medical Devices – Application of Risk Management to Medical Devices.

Sterilization Method:

Synergetics Disposable Spetzler Malis Standard Bipolar Forceps are sterilized in accordance with AAMI/ISO 11135 Medical Devices — Validation and routine control of ethylene oxide sterilization (EtO), Overkill Method.

Summary of Non-clinical Testing:

Bench testing, comparative performance testing to the predicate device, and relevant electrical safety testing to IEC 60601-1, Medical Electrical Equipment Part 1: General Requirements for Safety, IEC 60601-1-2, Medical Electrical Equipment Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility, and IEC 60601-2-2, Medical Electrical Equipment Part 2: Particular Requirements for the Safety of High Frequency Surgical Equipment was performed on the Synergetics Disposable Spetzler Malis Standard Bipolar Forceps. The non-clinical testing indicates the device performance is substantially equivalent to the predicate and the slight differences raise no new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Synergetics, Incorporated
% Mr. Gary Oliveros
Senior Regulatory Affairs Specialist
3845 Corporate Centre Drive
O'Fallon, Missouri 63368

JUL 10 2012

Re: K121426
Trade/Device Name: Synergetics Disposable Spetzler-Malis Standard Bipolar Forceps
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: May 11, 2012
Received: May 17, 2012

Dear Mr. Oliveros:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

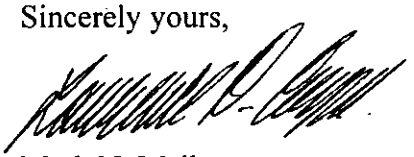
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



FOR Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Synergetics™

K121426

Synergetics™ 510 (k) Submission
Synergetics Disposable Spetzler-Malis Standard Bipolar Forceps
Section 4 - Indications for Use

510(k) Number (if known):

Device Name: Synergetics Disposable Spetzler–Malis Standard Bipolar Forceps

Indications for Use: The Synergetics Disposable Speztler–Malis Standard Forceps are single use devices sold sterile and are intended for use in electrosurgery for coagulation of tissue.

Prescription Use ____X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden for MXM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121426